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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,014	07/03/2003	Richard A. Earl	102258.156US1	5448
25270	7590	09/03/2004	EXAMINER	
EDWARD D GRIEFF HALE & DORR LLP 1455 PENNSYLVANIA AVE, NW WASHINGTON, DC 20004			HUANG, EVELYN MEI	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 09/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/612,014

Applicant(s)

EARL ET AL.

Examiner

Evelyn Huang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-57 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Election/Restrictions

1. Upon reconsideration of the claims in view of Applicant's remarks, restriction requirement under 35 U.S.C. 121 is restated as follows:

1. Claims 1-4, 55, 56 in part, drawn to a compound of formula I wherein R_n is a thienyl of formula 1 or 10, classified in class 549, subclass 71, and the composition thereof.
2. Claims 1-4, 55, 56 in part, drawn to a compound of formula I wherein R_n is a keto group of formula 2, 27, 22 or 38, classified in class 568, subclass 332, and the composition thereof.
3. Claims 1-4, 55, 56 in part, drawn to a compound of formula I wherein R_n is an isoindolyl of formula 3, classified in class 548, subclass 472, and the composition thereof.
4. Claims 1-4, 55, 56 in part, drawn to a compound of formula I wherein R_n is a heterocyclic tricyclic group of formula 4 or 51, classified in class 548, subclass 430, and the composition thereof.
5. Claims 1-4, 55, 56 in part, drawn to a compound of formula I wherein R_n is a pyrrolyl of formula 5, 29, 33, 45, classified in class 548, subclass 539, and the composition thereof.
6. Claims 1-4, 55, 56 in part, drawn to a compound of formula I wherein R_n is a S(O)_s containing group of formula 6, classified in class 568, subclass 27, and the composition thereof.
7. Claims 1-4, 55, 56 in part, drawn to a compound of formula I wherein R_n is a halo containing group of formula 7, classified in class 570, subclass 129, and the composition thereof.
8. Claims 1-4, 55, 56 in part, drawn to a compound of formula I wherein R_n is an indolyl of formula 8, 23, 24, classified in class 548, subclass 492, and the composition thereof.

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9. Claims 1-4, 55, 56 in part, drawn to a compound of formula I wherein R_n is a carboxzoyl of formula 9 or 28 classified in class 548, subclass 440, and the composition thereof.
10. Claims 1-4, 55, 56 in part, drawn to a compound of formula I wherein R_n is a ether containing group of formula 11, 12, 19, classified in class 568, subclass 631, and the composition thereof.
11. Claims 1-4, 55, 56 in part, drawn to a compound of formula I wherein R_n is an imidazopyridine of formula 13, classified in class 546, subclass 121, and the composition thereof.
12. Claims 1-4, 55, 56 in part, drawn to a compound of formula I wherein R_n is a 1,3 oxazolyl of formula 12, 39, 49, classified in class 548, subclass 235, and the composition thereof.
13. Claims 1-4, 55, 56 in part, drawn to a compound of formula I wherein R_n is a hydrocarbyl of formula 15, 35, class and subclass various dependent on the species elected, and the composition thereof.
14. Claims 1-4, 55, 56 in part, drawn to a compound of formula I wherein R_n is an amine containing group of formula 16, 20, 25, 27, classified in class 564, subclass 305, and the composition thereof.
15. Claims 1-4, 55, 56 in part, drawn to a compound of formula I wherein R_n is a carboxylic ester containing group of formula 18, classified in class 560, subclass 43, and the composition thereof.
16. Claims 1-4, 55, 56 in part, drawn to a compound of formula I wherein R_n is a benzoxazolyl of formula 21 or 42, classified in class 548, subclass 224, and the composition thereof.
17. Claims 1-4, 55, 56 in part, drawn to a compound of formula I wherein R_n is a benzopyrazolyl of formula 26, classified in class 548, subclass 361.5, and the composition thereof.
18. Claims 1-4, 55, 56 in part, drawn to a compound of formula I wherein R_n is a pyrrolyl of formula 29, 33, 45, classified in class 548, subclass 539, and the composition thereof.

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19. Claims 1-4, 55, 56 in part, drawn to a compound of formula I wherein R_n is a pyrazolyl of formula 30, 31, 40, 47, classified in class 548, subclass 373.1, and the composition thereof.
20. Claims 1-4, 55, 56 in part, drawn to a compound of formula I wherein R_n is a phenothiazinyl of formula 4 or 51, classified in class 548, subclass 430, and the composition thereof.
21. Claims 1-4, 55, 56 in part, drawn to a compound of formula I wherein R_n is a pyrrolyl of formula 32, 43, classified in class 544, subclass 38, and the composition thereof.
22. Claims 1-4, 55, 56 in part, drawn to a compound of formula I wherein R_n is a benzopyranylpiperidinyl of formula 34, classified in class 546, subclass 89, and the composition thereof.
23. Claims 1-4, 55, 56 in part, drawn to a compound of formula I wherein R_n is an oxygen containing tricyclic ring of formula 36, 37, classified in class 549, subclass 354, and the composition thereof.
24. Claims 1-4, 55, 56 in part, drawn to a compound of formula I wherein R_n is a 1, 2 thiazolyl of formula 41, 46, classified in class 548, subclass 202, and the composition thereof.
25. Claims 1-4, 55, 56 in part, drawn to a compound of formula I wherein R_n is a sulfur containing tricyclic ring of formula 44, classified in class 549, subclass 12, and the composition thereof.
26. Claims 1-4, 55, 56 in part, drawn to a compound of formula I wherein R_n is an amido containing group of formula 48, classified in class 564, subclass 182, and the composition thereof.
27. Claims 1-4, 55, 56 in part, drawn to a compound of formula I wherein R_n is an NOH containing moiety of formula 50, classified in class 564, subclass 297, and the composition thereof.

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28. Claims 1-4, 55, 56 in part, drawn to a compound of formula II wherein R_n is an amino containing group of formula 1, 2, 9, 12, 15, 18, 19, classified in class 564, subclass 431, and the composition thereof.
29. Claims 1-4, 55, 56 in part, drawn to a compound of formula II wherein R_n is a hydroxy containing group of formula 3, 4, 11, classified in class 568, subclass 335, and the composition thereof.
30. Claims 1-4, 55, 56 in part, drawn to a compound of formula II wherein R_n is a carboxy ester containing group of formula 5, 6, 17 classified in class 560, subclass 106, and the composition thereof.
31. Claims 1-4, 55, 56 in part, drawn to a compound of formula II wherein R_n is a nitrogen containing bicyclic group of formula 7, classified in class 548, subclass 452, and the composition thereof.
32. Claims 1-4, 55, 56 in part, drawn to a compound of formula II wherein R_n is a benzoindolyl of formula 8, classified in class 548, subclass 427, and the composition thereof.
33. Claims 1-4, 55, 56 in part, drawn to a compound of formula II wherein R_n is a pyridinyl of formula 10, 16 classified in class 546, subclass 310, and the composition thereof.
34. Claims 1-4, 55, 56 in part, drawn to a compound of formula II wherein R_n is an indolyl of formula 13, classified in class 548, subclass 494, and the composition thereof.
35. Claims 1-4, 55, 56 in part, drawn to a compound of formula II wherein R_n is a chloro containing group of formula 14, classified in class 570, subclass 183, and the composition thereof.
36. Claim 5, drawn to a method of treating or reducing inflammation, pain or fever using the compound of formula I or II, classified in class 514, subclass various depending on the species elected.

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37. Claims 6, 7, drawn a method for treating a gastrointestinal disorder using the compound of formula I or II, classified in class 514, subclass various dependent on the species elected.
38. Claims 8, 9, drawn to a method for facilitating wound healing with a compound of formula I or II, class 514, subclass various dependent on the species elected.
39. Claim 10, drawn to a method of treating or reversing gastrointestinal, renal and/or respiratory toxicity using the compound of formula I or II, classified in class 514, subclass various depending on the species elected.
40. Claims 11-14, drawn a method for treating an inflammatory disease using the compound of formula I or II, classified in class 514, subclass various dependent on the species elected.
41. Claim 15, drawn to a method for treating an ophthalmic disorder with a compound of formula I or II, class 514, subclass various dependent on the species elected.
42. Claims 16, 17, drawn to a composition comprising the compound of formula I or II of claim 1 and at lease one additional therapeutic agent, classified in class 514, subclass various dependent on the species elected.
43. Claim 18, drawn to a method of treating or reducing inflammation, pain or fever using the composition of claim 16, classified in class 514, subclass various depending on the species elected.
44. Claims 19, 20, drawn a method for treating a gastrointestinal disorder using the composition of claim 16, classified in class 514, subclass various dependent on the species elected.
45. Claims 21, 22 drawn to a method for facilitating wound healing with composition of claim 16, class 514, subclass various dependent on the species elected.
46. Claim 23, drawn to a method of treating or reversing gastrointestinal, renal and/or respiratory toxicity using the composition of claim 16, classified in class 514, subclass various depending on the species elected.

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47. Claims 24-27, drawn a method for treating an inflammatory disease using the composition of claim 16, classified in class 514, subclass various dependent on the species elected.
48. Claim 28, drawn to a method for treating an ophthalmic disorder with a composition of claim 16, class 514, subclass various dependent on the species elected.
49. Claims 29-37, drawn to a composition comprising the compound of formula I or II of claim 1 and at least one compound that donates, transfers or release nitric oxide, classified in class 514, subclass various dependent on the species elected.
50. Claims 38, 39, 57, drawn to a composition of claim 29 further comprising at least one therapeutic agent, classified in class 514, subclass various dependent on the species elected.
51. Claim 40, drawn to a method of treating or reducing inflammation, pain or fever using the composition of claim 29 or 38, classified in class 514, subclass various depending on the species elected.
52. Claims 41, 42, drawn a method for treating a gastrointestinal disorder using the composition of claim 29 or 38, classified in class 514, subclass various dependent on the species elected.
53. Claims 43, 44 drawn to a method for facilitating wound healing with composition of claim 29 or 38, class 514, subclass various dependent on the species elected.
54. Claim 45, drawn to a method of treating or reversing gastrointestinal, renal and/or respiratory toxicity using the composition of claim 29 or 38, classified in class 514, subclass various depending on the species elected.
55. Claims 46-49, drawn a method for treating an inflammatory disease using the composition of claim 29 or 38, classified in class 514, subclass various dependent on the species elected.

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56. Claim 50, drawn to a method for treating an ophthalmic disorder with a composition of claim 29 or 38, class 514, subclass various dependent on the species elected.
57. Claims 51-54, 58, drawn to a kit comprising the compound claim 1 or 55, or a composition thereof with additional active ingredients, class 424, subclass various depending on the species elected.

The inventions are distinct, each from the other because of the following reasons:

The compounds of Group 1-27 of formula I and Group 27-35 of formula II are chemically, physically and patentably distinct that they are classified in different classes and subclasses. They are prepared by different methods and known to have different utilities. A reference anticipating a compound of one group would not render obvious the compound of the other groups.

Inventions 1-35 and inventions 36-41 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different processes, such as treating pain, fever, an inflammatory disease, a gastrointestinal disorder, or an ophthalmic disorder etc.

Inventions 42 or 49-50 and inventions 43-48 or 51-56 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different processes, such as treating pain, fever, an inflammatory disease, a gastrointestinal disorder, or an ophthalmic disorder etc.

Inventions 1-35, 42, 49-50 and invention 57 are patentably distinct since products other than the compounds of Group 1-35 or compositions of Group 42, 49, 50 can be used to make the kits.

The Group 42, 49, 50 composition each has different multiple active ingredients. The patentability of Group 42, 49, 50 depends on the type and amount of the specific multiple active ingredients, their interaction, co-action, e.g. synergism etc., which is patentably distinct from the Group 1-35 compositions containing only a single active ingredient.

Because these inventions are distinct for the reasons given above, the search is not co-extensive and is burdensome. Since the search required for one group is not required for the other groups, restriction for examination purposes as indicated is proper.

2. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

If Applicants were to elect from Group 1-35, election of a species compound is required. Further restriction within the elected group may also be required.

If Applicants were to elect from the method of Group 36-41, 43-48, 51-56, election of a species compound and election of a single disease within the elected Group would be required. Further restriction may also be required.

If Applicants were to elect from the composition of multiple active ingredients of Group 42, 49, 50, election of a species compound of formula I or II and election of a single additional active ingredient would be required. Further restriction may also be required.

If Applicants were to elect Group 57, election of a species compound of formula I or II and election of a single additional active ingredient would be required. Further restriction may also be required.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Evelyn Huang

Primary Examiner

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